K071706

DEC 2 0 2007

Summary of 510(k) Safety and Effectiveness Information

Envoy® 500 HDL Cholesterol Reagent and Envoy® 500 HDL Calibrator

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitted by:

Vital Diagnostics, Inc.
1075 West Lambert Road, Building D
Brea, California 92861

Contact Person: Wynn Stocking
Regulatory Affairs Manager

Date Submitted: December 4, 2007

Device Names:

Proprietary names: Envoy® 500 HDL Cholesterol Reagent Kit, and
Envoy® 500 HDL Calibrator Kit

Common names: High density lipoprotein (HDL) cholesterol reagent and
High density lipoprotein (HDL) cholesterol calibrator

Classification names: LDL & VLDL precipitation, cholesterol via esterase-oxidase, HDL, and
Calibrator, primary

Device Description:

The Envoy® 500 HDL Cholesterol Reagent is a two-part reagent that is calibrated with the Envoy® 500 HDL Calibrator for use with the Envoy® 500 Chemistry System. This reagent determines high density lipoprotein cholesterol through the accelerator selective detergent methodology. This procedure measures HDL-cholesterol in a two step reaction sequence. In the first step, non-HDL cholesterol is rendered non-reactive. In the second step, HDL cholesterol is solubilized using a selective detergent and reacts to produce a red chromogen.

Intended Use:

The Envoy® 500 HDL Cholesterol Reagent and Calibrator are for the quantitative determination of high density lipoprotein (HDL) cholesterol in serum and plasma using the Envoy® 500 Chemistry System. HDL Cholesterol measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases, and for the assessment of the risk of developing cardiovascular disease.

Predicate Device:

The Envoy 500 HDL Cholesterol Reagent and Calibrator are substantially equivalent to the Genzyme Ultra N-geneous HDL Cholesterol Reagent, product nos. 80-6283-00 and 80-6277-00 and the Genzyme Ultra N-geneous HDL Cholesterol Calibrator, product no. 80-6449-00, which are currently marketed by Genzyme Corporation of Cambridge, MA.

Summary of Performance Data:

The effectiveness of Envoy® 500 HDL Cholesterol Reagent and the Envoy® 500 HDL Calibrator for the Envoy® 500 Chemistry System is shown by the following studies.

Usable Range

The linear range of the Envoy 500 HDL Cholesterol Reagent is from 5 to at least 150 mg/dL, as shown by the recovery of linearity related solutions that span the linear range. Least squares regression statistics compare recoveries to the dilution factors of a set of reference pools prepared by diluting a human HDL cholesterol concentrate with stripped human serum pool.

(Envoy Recoveries) = -0.6 mg/dL + 19.284 x (Dilution Factor),
r = 0.9998, $s_{y.x}$ = 1.11 mg/dL, n = 44, range = 0.1 to 173.5 mg/dL

Limit of Detection

The limit of detection (LoD) for HDL cholesterol was determined based on CLSI protocol EP17-A. Forty blank samples and 40 low level samples were assayed. The Limit of Blank (LoB) is 0.29 mg/dL. The reported LoD is 0.46 mg/dL with proportions of false positives *(α)* less than 5% and false negatives *(β)* less than 5%.

Precision

Precision is demonstrated by the replicate assay of commercially available control sera. Precision statistics, calculated analogous to the method described in NCCLS Guideline EP3-T, are shown below.

			Within Run		Total	
Sample	n	mean	1SD	%CV	1SD	%CV
Level 1	45	36.8	0.52	1.4%	0.72	2.0%
Level 2	48	71.1	0.68	1.0%	1.25	1.8%

Correlation

Mixed serum and plasma specimens, collected from adult patients, were assayed for HDL cholesterol using the Envoy 500 HDL cholesterol application and another commercially available method. Results were compared by least squares linear regression and Passing-Bablok regression and the following statistics were obtained.

Least Squares Linear Regression

Envoy 500 = 0.7 mg/dL + 1.021 × Competitive Method
r = 0.995 $s_{(y.x)}$ = 2.42 mg/dL n = 312 range = 5 - 158 mg/dL
95% CI y-intercept: 0.07 to 1.38 mg/dL 95% CI slope: 1.010 to 1.032

Passing - Bablok Regression

Envoy 500 = 0.7 mg/dL + 1.015 × Competitive Method
95% CI y-intercept: 0.2 to 2.0 mg/dL 95% CI slope: 1.000 to 1.029

Stability

The 14 day onboard reagent stability and 7 day calibration stability claims are documented through the assay of serum controls over the claimed periods. In all cases, statistical estimates of total imprecision are less than 1.5 mg/dL.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Clinical Data, Inc.
c/o Mr. Wynn Stocking
Manager, Regulatory Affairs
1075 West Lambert Road, Building D
Brea, CA 92821

Re: k071706
Trade Name: Envoy® 500 HDL Cholesterol Reagent Kit and Envoy® 500 HDL Calibrator
Regulation Number: 21 CFR 862.1475
Regulation Name: Lipoprotein test system
Regulatory Class: Class I, subject to limitation to exemption in 21 CFR 862.9(c)(4)
Product Code: LBS, JIT
Dated: November 14, 2007
Received: November 15, 2007

Dear Mr. Stocking:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K071706

Device Name: Envoy® 500 HDL Cholesterol Reagent and
Envoy® 500 HDL Calibrator

Indication For Use:
The Envoy® 500 HDL Cholesterol Reagent and Envoy® 500 HDL Calibrator are intended for use with the Envoy® 500 Chemistry System as a system for the quantitative determination of high density lipoprotein (HDL) cholesterol in serum and plasma. HDL cholesterol measurements are used in the diagnosis and treatment of lipid disorders (such as diabetes mellitus), atherosclerosis, and various liver and renal diseases, and for the assessment of the risk of developing cardiovascular disease.

This reagent is intended to be used by trained personnel in a professional setting and is not intended for home use.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K071706